



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0336]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim “Healthy” on Packaged Foods

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, we, or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a new collection of information for a study entitled “Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim ‘Healthy’ on Packaged Foods.”

**DATES:** Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2021-N-0336 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim ‘Healthy’ on Packaged Foods.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim “Healthy”  
on Packaged Foods

OMB Control Number 0910-NEW

Section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(r)(1)(A)) permits the use of label and labeling claims that characterize the level of a nutrient in a food when the claims are made in accordance with FDA's regulations. Such claims are referred to as "nutrient content claims." We have issued regulations under section 403(r)(1)(A) of the FD&C Act defining "implied nutrient content claims" as those that imply that a food, because of its nutrient content, may be useful in achieving a total diet that conforms to current dietary recommendations ("Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms," 58 FR 2302 at 2374, January 6, 1993). We have determined that a claim that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices is clearly a claim that characterizes the level of nutrients in that food. The claim is essentially saying that the level of nutrients in the food is such that the food will contribute to good health (58 FR 2302 at 2375). In 1994, we issued a definition of "healthy" as an implied nutrient content claim (59 FR 24232, May 10, 1994); the regulation is codified at 21 CFR 101.65(d)(2).

In 2018, we announced our Nutrition Innovation Strategy (<https://www.fda.gov/food/food-labeling-nutrition/fda-nutrition-innovation-strategy>) outlining key priorities the Agency intended to pursue to reduce the burden of chronic disease through improved nutrition and advance its public health mission. To help advance these goals, we are exploring the development of a graphic symbol to help consumers identify packaged food products that meet FDA's definition of "healthy." The symbol would be a graphic representation of the nutrient content claim "healthy" and, like the implied nutrient content claim "healthy" itself, would be voluntary for packaged food companies. Companies could voluntarily use the symbol on food products that meet FDA's definition of "healthy."

In 2019 and 2020, FDA conducted a review of the literature on front-of-package (FOP) nutrition-related symbols and conducted a series of focus groups to test symbol concepts and

draft FOP symbols (see Docket No. FDA-2021-N-0336 for a table of draft FOP symbols and the literature review).

As part of its efforts to promote public health, FDA proposes to conduct three consecutive quantitative research studies--an experimental study and two surveys--to explore consumer responses to the draft FOP symbols that manufacturers could voluntarily use on a food product as a graphic representation of the nutrient content claim “healthy.” If research results suggest the need, the symbols will be fine-tuned following the experimental study and again fine-tuned following each survey. The first study will be a controlled, randomized experiment (hereafter called Study 1). Study 1 will use a 15-minute web-based questionnaire to collect information from 5,000 U.S. adult members of an online consumer panel maintained by a contractor. The surveys, Studies 2 and 3, will each utilize the same instrument, a 10-minute questionnaire, to test sets of draft FOP symbols. Studies 2 and 3 will each draw a sample of 1,000 U.S. adult participants from an online consumer panel.

Conditions for Study 1 will be: (1) a set of draft FOP symbols, including “no-symbol” controls; (2) three types of mock food products (i.e., a breakfast cereal, a frozen meal, and a canned soup); (3) a “no-information” condition where no explanation of the symbol is provided; and; (4) a Uniform Resource Locator (URL) condition, in which a URL is tested alongside the symbol. Each participant in Study 1 will be randomly assigned to a condition, which will include viewing a label image and responding to various measures of the symbol’s effectiveness. Product perceptions (e.g., healthfulness and contribution to a healthy diet), label perceptions (e.g., believability and trustworthiness), and purchase/choice questions will constitute the measures of response in the experiment. The instrument will also collect information from participants about their history of purchasing or consuming similar products; nutrition knowledge; dietary interests; motivation regarding label use; health status; and demographic characteristics.

Studies 2 and 3 will utilize non-probability survey methods, using a web-based panel to

draw a sample of U.S. adults ages 18 and older who self-identify as primary food shoppers. The sample will be balanced to the demographics of the U.S. population. The survey instruments will focus on clarity, relevance, and appeal of a small subset of revised symbols.

The studies are part of our continuing effort to enable consumers to make informed dietary choices and construct healthful diets. We intend to use the results to inform our continued exploration of a symbol manufacturers could voluntarily use to represent the nutrient content claim “healthy” on the food label. We will not use the results to develop population estimates.

*Description of Respondents:* Respondents to this collection of information include members of the general public.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Study 1 (Experiment) Cognitive interview screener	75	1	75	0.083 (5 minutes)	6
Study 2 (Survey) Cognitive interview screener <sup>2</sup>	75	1	75	0.083 (5 minutes)	6
Study 1 (Experiment) Cognitive interview	9	1	9	1	9
Study 2 (Survey) Cognitive interview	5	1	5	1	5
Study 1 (Experiment) Pretest	180	1	180	0.25 (15 minutes)	45
Study 2 (Survey) Pretest <sup>2</sup>	25	1	25	0.17 (10 minutes)	4
Study 1 (Experiment)	5,000	1	5,000	0.25 (15 minutes)	1,250
Study 2 (Survey)	1,000	1	1,000	0.17 (10 minutes)	170
Study 3 (Survey)	1,000	1	1,000	0.17 (10 minutes)	170
Total					1,665

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Since Study 3 is identical to Study 2, only one set of cognitive interviews and pretests are needed.

Dated: April 30, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*